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CVR. nr. 63644919

EU Declaration of Conformity

No.: REG-004387

We

Manufacturer:	Ambu A/S
Single Registration number	DK-MF-000001437
Postal address:	Baltorpbakken 13
City, country:	2750, Ballerup, Denmark
Telephone number:	+45 72252000
E-mail address:	ambu@ambu.com

declare that the declaration is issued under the sole responsibility and belongs to the following devices:

Product name	Ambu® Redi-ACE ™
Intended purpose	The Ambu Redi-ACE is a one-piece rigid cervical spine immobilization device designed to assist the rescuer with the maintenance of neutral alignment, prevention of lateral (side-to-side) sway and anterior-posterior (forward and backward) flexion and extension of the cervical spine during patient transport or movement.
Catalogue number(s)	472001000 472002000
Device risk class	Class [1] (rule 1, Annex VIII)
Basic UDI-DI	5707480301000051068
GMDN code and term	45129 Cervical spine collar, single-use

The devices covered by the present declaration is in conformity with the requirements specified in the relevant Union legislation:
Medical Device Regulation 2017/745

Conformity assessment procedure:
Class I, non-sterile: Annex II and III,

Signed for and behalf of Amby A/S:

Ballerup, Denmark	2021-02-23	
[place of issue]	[Date of issue]	Katrine Dalsgaard Ajbro, Head of Regulatory Affairs Operation

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